DEC 13 2006

Appendix E

510(k) Summary

Date:	September 7, 2006
	Aspect Medical Systems, Inc., 141 Needham St., Newton, MA 02464
Contact Person:	Renee Gould (617) 559-7788
Proprietary Name:	BIS Bilateral Sensor
Common Name:	Electrode, Cutaneous Electrode
Classification:	Class II device. Refer to 21 CFR 882.1320
Product Code:	GXY
Predicate Device:	K002734, Aspect Enhanced XP BIS Sensor cleared September 14, 2000
Device Description:	The Sensor is a single patient use, disposable, pre-gelled 6 electrode array that is applied directly to the patient's forehead to record electrophysiological signals. It has an electronic smart card memory device in the tab area that contains configuration and identification information.
Indications for Use:	The BIS Bilateral Sensor is applied directly to the patient's skin to enable recordings of electrophysiological (such as EEG) signals.

Similarities:

- same indications for use,
- same intended use,
- same fundamental scientific technology,
- incorporates the same basic design,
- 2 channels of BIS,
- incorporates the same materials and biocompatibility,
- has the same shelf life,
- is packaged using the same materials and processes, and
- incorporates smart card memory device.

Differences:

- addition of montage on the other side of the head,
- addition of the 2 electrodes, and
- 4 channels of EEG collected.

In summary, the BIS Bilateral Sensor is substantially equivalent to the predicate device. Aspect Medical Systems believes these modifications do not raise new questions of safety or effectiveness. The intended use is the same as the predicate device. The indications for use remain the same as the Enhanced Sensor. The fundamental scientific technology remains the same as the Enhanced Sensor predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2006

Aspect Medical Systems, Inc.
% Ms. Renee Gould
Director, Regulatory, Quality Assurance
141 Needham Street
Newton, Massachusetts 02464

Re: K062692
Trade/Device Name: BIS Bilateral Sensor
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: November 9, 2006
Received: November 13, 2006

Dear Ms. Gould:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

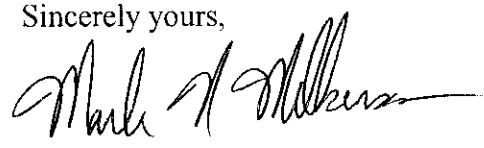
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or 240-276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix C

Indications for Use Statement

510(k) Number (if known) K062692

Device Name BIS Bilateral Sensor

Indications For Use

The BIS Bilateral Sensor is applied directly to the patient's skin to enable recordings of electrophysiological (such as EEG) signals.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062692